Corporate Integrity™

2012-09

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GRC Vendor Analyzer: *QUMAS ComplianceSP Bringing Collaboration and Compliance Together*

"Corporate Integrity finds that the QUMAS ComplianceSP solution brings harmony to the dissonance and tension between collaboration and compliance in life sciences and other regulated industries."

Collaboration and Compliance — Competing or Complementary Goals?

Organizations across industries are challenged to be collaborative — particularly across extended business relationships (e.g., vendors, suppliers, contractors, outsourcers and service providers). This is a particular trend in life sciences, as core processes such as research and development, clinical trials, and manufacturing are reengineered and extended across business relationships. Since modern life science organizations do not have brick and mortar boundaries, it is difficult to understand where the organization starts and stops, as it is comprised of a myriad of complex business relationships and collaborations.

Collaboration combined with compliance demands in life sciences could reasonably be expected to bring business to a screeching halt. Collaboration could create so many issues that the organization is constantly fighting compliance fires under a continuous scope of regulator scrutiny.

Success in modern life sciences organizations depends on the ability to efficiently and effectively manage a large number of documents and comply with numerous regulations that govern the organization across collaborative relationships and entities. The demands upon the modern life science organization is legion, and covers the spectrum of:

- **A dynamic and distributed business environment:** The life science organization is a network of business relationships that demand collaboration and information sharing while requiring strict oversight, documentation and control of processes.
- **Highly regulated environment:** Virtually every aspect of life sciences faces regulatory oversight — from research and development, manufacturing, clinical trials, all the way through marketing and sales.
- **Defensible data:** The organization has to have detailed documentation and validation of business processes and be ready to provide audit trails, evidence and documentation at a moment's notice.
- **Defined and communicated policies and procedures:** The organization must document every aspect of core processes. Deviations and exceptions must be recorded, approved and monitored. Accountable roles must understand what is required of them and are trained appropriately.
- **Corrective actions and preventative actions:** Organizations need established procedures in place to correct noncompliant conditions and prevent further issues from happening. This requires a detailed issue management and resolution process.

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- **Business risk and regulatory intelligence:** Like any organization, the modern life science organization needs to ensure it is managing its business according to expected objectives. It also must monitor a constantly changing risk and regulatory environment to ensure the business maintains compliance in the midst of change.
- **Effective document management:** The organization must minimize managing and processing documents manually to ensure nothing slips through the cracks. This includes managing the risk of unauthorized access to documents with full traceability through version control and workflow.
- **Faster time-to-market:** The life science organization requires agile business processes that deliver fast time-to-market for new products. Document completion time must be fast and accurate.

Often life science organizations have implemented Microsoft SharePoint in an ad hoc manner to meet immediate collaboration needs. SharePoint is a natural solution as it is readily available, easy to use and integrates seamlessly in a predominantly Microsoft environment; or so it seems, until compliance begins asking questions about traceability, accountability and audit. Regulatory requirements such as FDA 21 CFR Part 11 and SharePoint can make collaboration a compliance nightmare.

QUMAS ComplianceSP Delivers Integrated Collaboration and Compliance

The right compliance and collaboration technology delivers a process, technology and information architecture that can be used for a range of initiatives. An integrated collaboration and compliance architecture can enable a collaborative, better performing, efficient, flexible and fully compliant business environment. Effective compliance management requires the ability to meet requirements, achieve human and financial efficiency in compliance and business processes, and meet the demands of a dynamic business environment that requires collaboration while being able to demonstrate compliance at a moment's notice.

QUMAS ComplianceSP is a GRC solution Corporate Integrity has researched, evaluated and reviewed. QUMAS delivers on the vision of GRC in life sciences to provide a robust collaboration and compliance technology architecture. It enables business and compliance processes to be agile, efficient and effective in distributed and dynamic business relationships while managing regulatory requirements, compliance and process risks, as well as documentation and control. Corporate Integrity finds that the QUMAS ComplianceSP solution brings harmony to the dissonance and tension between collaboration and compliance in life sciences and other regulated industries.

QUMAS ComplianceSP provides a collaboration and compliance platform by integrating SharePoint 2010 with QUMAS compliance technology. It delivers compliance management, documentation and processes management, and analytical tools needed to deliver on the goals of collaboration and compliance. What would appear to be diametrically opposed goals can act in harmony, delivering agility and efficiency to the organization while effectively meeting compliance demands. Clients deploy QUMAS ComplianceSP for an integrated view of collaboration and compliance and to address exposures, ensure compliance with regulations, improve human and financial efficiencies, enhance transparency and manage GRC in the context of extended business relationships and change.

With a leadership position in life sciences, QUMAS has nearly 20 years of experience delivering innovative GRC technology to meet the demands of highly regulated and dynamic life science organizations. Corporate Integrity has interacted and engaged several QUMAS customers and finds them to be satisfied with the product and its ability to deliver value. While many GRC vendors stretch themselves thin by attempting to be all things to all industries — often promising more than they can deliver — QUMAS demonstrates focus and control to deliver specific compliance and business needs for the modern life science organization.

QUMAS clients report achieving value in their QUMAS ComplianceSP implementations. In particular, QUMAS has enabled clients to efficiently manage all of their documents electronically whether they are in the hundreds or tens-of-thousands as well as electronically managing deviations and CAPAs. QUMAS ComplianceSP provides an integrated collaboration, process, information and technology architecture that bring compliance, process and business activities together through clear accountability in workflow, task and project and program management.

QUMAS Compliance Platform Capability Analysis

Through an integrated QUMAS and Microsoft SharePoint 2010 solution, QUMAS ComplianceSP makes collaboration compliant to the host of requirements bearing down on life science organizations. QUMAS ComplianceSP is ideally suited for organizations that operate in highly collaborative, regulated, dynamic and distributed environments. QUMAS ComplianceSP achieves this through the following core capabilities:

- **Integration:** ComplianceSP leverages complete integration between SharePoint 2010 and Microsoft Office, allowing individuals to use Microsoft technologies as designed while ensuring compliance.
- **Leveraging the platform:** ComplianceSP takes advantage of the functional richness of SharePoint 2010 and draws upon its capabilities of records management, team/project management, and work scheduling tools to leverage relevant functionality that is complementary to the compliance management capability provided by QUMAS.
- **Enterprisewide access:** ComplianceSP can incorporate information from a wide variety of related enterprise applications through SharePoint Business Connectivity Services (BCS), which supports connectivity to a variety of enterprise systems, allowing real-time visibility and information exchange with LIMS, ERP and HR systems.
- **Industry support:** The industry support for SharePoint means ComplianceSP organizations can take advantage of a rich selection of third-party tools and technologies to offer complementary functionality and harness the extensive technical and consulting expertise in the industry.
- **Collaboration and content repository for documents:** Organizations can implement a single cohesive system for managing the complexities of life science documents through a consistent platform that provides ease of use and collaboration with the ability to manage access and audit trails for compliance.
- **Business and compliance lifecycle management:** QUMAS integrates business and compliance processes vital for life sciences. This means controlling processes and documents throughout their lifecycles while leveraging Microsoft technology platforms.
- **Business process automation and workflow:** QUMAS ComplianceSP delivers workflow and task management to ensure controls are implemented and followed throughout business and operations.
- **Traceability and accountability:** The solution provides a robust audit trail to document who viewed, reviewed and approved documents and processes, a listing of key decisions made, and details about revisions and sign-offs.
- **Forms processing and management:** QUMAS offers creation and use of forms in SharePoint to automate business and compliance processes, and routes requests and information for approval, and other steps for authorization.
- **Integrated learning management:** QUMAS ComplianceSP integrates learning content and compliance documentation into processes, ensuring individuals access to learning modules.
- **Dashboard and reporting:** QUMAS ComplianceSP delivers configurable reporting and a dashboard to give business and compliance personnel the information they need when they need it across collaboration portals.
- **Track and interpret regulations:** QUMAS enables organizations to manage regulatory change as they face changing laws, regulations and enforcement actions and must ensure business processes are current and relevant.
- **Capture exceptions and deviations:** QUMAS has a complete system to capture issues, incidents, exceptions and deviations and ensure they are responded to.
- **Audit and investigate:** Through complete audit, assessment, and management capabilities, QUMAS ComplianceSP provides a consistent application to manage assessment, audit, monitoring and investigation processes.
- **Measure, assess and implement change:** Life science organizations are constantly changing. Business, technology, employees, relationships and the regulatory and risk environment are in a constant state of flux. QUMAS ComplianceSP delivers a solution to profile and manage change to keep the organization compliant.

QUMAS ComplianceSP brings together the needs of collaboration and compliance for life science organizations. While designed to help life science companies be compliant, QUMAS is more than that; it enables effective collaboration using the tools users want from popular Microsoft technologies in the context of a highly regulated, dynamic and distributed business environment. From a compliance perspective alone it is a worthy candidate for any compliance program. Combined with its breadth of process and document capabilities, QUMAS ComplianceSP enables collaboration, information management, analytics and insight while delivering value to the business to support the modern life sciences organization.

About QUMAS . . .

QUMAS delivers a closed-loop compliance model that standardizes and integrates the common elements of compliance tasks across the organization. Enterprises are able to effectively converge all of their compliance programs onto a single platform, radically reducing the cost of compliance and creating competitive advantage. With its proven track record in two of the of the most stringently regulated industries - financial services and life sciences - QUMAS has proven that it is best positioned to provide centralized compliance for any company, regardless of industry. Its solutions ensure corporate compliance with the full spectrum of global regulations.

The QUMAS solution facilitates an informed, risk-based response to compliance challenges across any business. The QUMAS Compliance Framework channels and focuses resources, providing certainty to a company's state of compliance as well as meaningful reporting to stakeholders. The result is an optimized closed-loop compliance environment.

With the QUMAS closed-loop compliance environment, the goal is to provide organizations with a complete and comprehensive view of compliance and serve as the compliance system of record when dealing with regulatory bodies.

About Corporate Integrity . . .

Corporate Integrity, LLC is a GRC strategy advisory firm providing leadership in education, research, analysis, and advisory services by monitoring the challenges and trends in business for corporate governance, risk management, and compliance (GRC).

Through ongoing research, interactions, and analytics, Corporate Integrity is the authority in understanding how organizations can foster a culture that "walks the talk," where integrity is central to GRC practices. Corporate Integrity educates organizations — and GRC professionals within those organizations — on achieving sustainability, consistency, efficiency, and transparency in their corporate GRC practices to maintain a position of integrity aligned with corporate values and business performance.

About Michael Rasmussen . . .

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Michael Rasmussen is an internationally recognized pundit on the topics of business ethics, corporate culture, policy management, and compliance. With more than 18 years of experience, Michael helps organizations understand their culture and improve related governance, risk, and compliance (GRC) strategies, processes, and technologies that deliver business agility, efficiency, and effectiveness. He is a sought-after keynote speaker, author, and advisor on compliance and risk management strategies. He is noted for being one of the earliest advocates for a collaborative and integrated approach to GRC.